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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,648	09/24/2001	Robert F. Sak	004122.00006	6515
22907	7590	09/02/2004	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Yw

<b>Office Action Summary</b>	<b>Application No.</b> 09/960,648	<b>Applicant(s)</b> SAK, ROBERT F.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Terminal Disclaimer***

1. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:
2. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

***Claim Objections***

3. Claims 1 and 29 are objected to because of the following informalities: In Claim 1, the current claim language as follows constitutes an intended use of the claimed element: "for being", "for guiding", "for obtaining", "for mating" and "for grasping". In order to overcome the following rejection, the claim should be amended as follows: in line 3, "for being removably" should read as "~~for being~~ removably"; in line 5, "for guiding" should read as "~~for~~ guiding"; in line 6, "for being slidably" should read as "~~for being~~ slidably"; in line 8, "for obtaining" should red as "~~for~~ obtaining"; In line 9, "for mating" should read as "~~for~~ mating"; and in line 11, "for grasping" should read as "~~for~~ grasping". Likewise, in Claim 29, the current claim language as follows constitutes an intended use of the claimed element: "for being", "for obtaining", "for mating", and "for grasping". In order to overcome the below rejection, the claim should be amended as follows: in line 2, "for being slidably" should read as "~~for being~~ slidably"; in line 3, "for obtaining" should read as "~~for~~ obtaining"; in line 5, "for mating" should read as "~~for~~ mating"; and in line 6, "for grasping" should read as "~~for~~ grasping".

Appropriate correction is required.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No.

6,302,853 to Sak. Although the conflicting claims are not identical, they are not patentably distinct from each other because Sak claims a cervical sampling apparatus comprising a vaginal insertions tube, an introduction guide and a cervical sampler.

6. Claims 20-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 and 33 of U.S. Patent No. 6,302,853 to Sak in view of Schuster et al. Sak claims a method of obtaining cervical samples comprising inserting an introduction guide member, introducing a vaginal insertion tube, inserting a cervical sampling member and extending a sample collecting member. Sak does not claim applying an ethanol based fixative onto the

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cervical sampling member after removal. Schuster et al teach applying an ethanol based fixative after removal of the cervical sampling member to prefix the cells. See Column 4, lines 5-8. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sak with the application of an ethanol based fixative, as taught by Schuster et al, to prefix the cells.

7. Claim 28 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 and 33 of U.S. Patent No. 6,302,853 to Sak in view of Schuster et al and Hasselbrack. Sak claims a method of obtaining cervical samples comprising inserting an introduction guide member, introducing a vaginal insertion tube, withdrawing the introduction guide member, advancing the vaginal insertion tube, inserting a cervical sampling member and extending a sample collecting member. Sak does not claim applying an ethanol based fixative onto the cervical sampling member after removal. Schuster et al teach applying an ethanol based fixative after removal of the cervical sampling member to prefix the cells. See Column 4, lines 5-8. Sak and Schuster do not teach spraying the ethanol based fixative. However, Hasselbrack discloses spraying a fixative to preserve the sample. See Column 7. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sak with applying an ethanol based fixative, as taught by Schuster et al, and spraying the fixative, as taught by Hasselbrack, to prefix the cells and to provide an even distribution of the fixative on the sample.

***Claim Rejections - 35 USC § 102 & 35 USC § 103***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 4-7, 15 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ko et al.

Ko et al disclose a tissue or mucus sampling device and further disclose a vaginal insertion tube; an introduction guide member; a cervical sampler; the cervical sampler comprising a sample collecting member, a forward end and a rear end for grasping by the operator; the rear end of the cervical sampler includes a handle; the holder mates with the sampling collecting member such that the sample collecting member rotates when the handle is rotated; the cervical sampler further includes at least two alignment members that align the cervical sampler with a longitudinal axis of the vaginal insertion tube when the cervical sampler is positioned within the vaginal insertion tube; the alignment members are integrally formed with an elongated portion of the cervical sampler; and the sample collecting member includes a cervical sample brush.

11. Claim 29 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zwick.

Zwick discloses a endocervical curette and further discloses a cervical sampler; the cervical sampler comprising a sample collecting member; and a forward end of the cervical sampler including a holder with projections and a rear end for grasping by a user. See Column 2, lines 4-7; and Abstract.

It would have been obvious matter of design choice to one of ordinary skill in the art to utilize hemispherical projections on the forward end of the cervical sampler because the Applicant has not disclosed that a hemispherical projection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the use of cooperating notches and protrusions because both hemispherical projections and cooperating notches and protrusions prevent movement of the tip as well as provide a means of attaching the tip to the holder.

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ko et al as applied to claim 1 above, and further in view of Marx.

Ko et al, as discussed above, disclose a means of obtaining a cervical sample, but fail to disclose an insertion position indicator located along a length of the vaginal insertion tube.

Marx discloses an endometrial tissue sampling device and further discloses the use of an insertion position indicator located along a length of the vaginal insertion tube. See Column 1, line 68; and Column 2, line 1.

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Since both Ko et al and Marx disclose means of sampling gynecological tissue, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ko et al to include the use of a depth scale, as per the teachings of Marx, since it would provide a means of allowing the user to have the ability to gauge the insertion depth of the instrument.

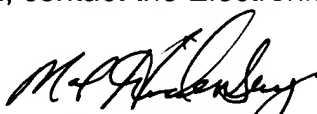
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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